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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,669	11/01/2001	Robert H. Broyles	OKL010-107/00727A	5327
53190	7590	07/12/2006	EXAMINER	
BARBARA KREBS YUILL 114 N.W. SIXTH STREET, SUITE 203 OKLAHOMA CITY, OK 73102			LI, QIAN JANICE	
			ART UNIT	PAPER NUMBER

1633

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/003,669	Applicant(s) BROYLES ET AL.	
	Examiner Q. Janice Li, M.D.	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 19, 22, 24, 25, 26, and 27 is/are pending in the application.
- 4a) Of the above claim(s) 11, 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 19, 22, 24, 25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/20/06 has been entered.

Claim 1 has been amended. Claims 1, 19, 22, 24, 25, 27 are under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 19, 24, 25, and 27 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record and following.

In the Remarks filed 4/20/06, applicant first cited *In re Brana*, arguing that if a statement of utility is made, the utility of the invention is presumed to be true as stated in the specification.

In response, it is the duty of the patent Office to evaluate the enablement or lack thereof the asserted utility. In the instant case, the Office has considered the asserted utility in direct accordance to the factors outlined in *In re Wands*, namely 1) the nature of the invention, 2) the state of the prior art, 3) the predictability of the art, 4) the amount of direction or guidance presented, and 5) the presence or absence of working examples, and presented detailed scientific reasoning for the finding of lacking enablement of the instantly claimed invention, supported by publications from prior and post-filing art. The *Wands* analysis and supporting specific evidence have been presented previously, and will not be reiterated.

Applicant then argues that in *In re Brana*, the court concluded that the PTO had erred and that the applicant's disclosure complied with the enablement requirements of § 112, first paragraph, and the underlying utility requirement.

In response, as an initial matter, it is noted that in *In re Brana*, the claims are rejected for lack of utility, and the court concluded there is nothing on record that would cause one of ordinary skill in art to reasonably doubt asserted utility. This is not the case for instant application, where the Office has cited numerous prior and post-filing art providing a reasonable double as to why the claimed invention was not enabled at the time of filing. Further, *In re Brana* case law discusses whether the test in animals would be sufficient to convince one skilled in art of asserted utility; absence of evidence that claimed compounds have chemotherapeutic effect in humans. While instant disclosure as filed does not has any *in vivo* data for the claimed invention, either in animals or in humans. Accordingly, *In re Brana* does not support applicant's argument.

In addition to numerous cited art of record, the following teaching further supports the Office position that the claimed method was not enabled as instant disclosed. Instant claims call for exposing ferritin-H to a globin-producing cell, preferably an erythroid precursor cell, or injecting ferritin-H *in vivo* for treating sickle cell disease, known as sickle cell anemia, a chronic, usually fatal anemia. *Broxmeyer et al* (PNAS 1991;88:770-4) teach exposing ferritin-H to erythroid precursor cells cause significant suppression of bone marrow erythroid precursor cells *in vitro* (e.g. table 2, results under BFU-E and CFU-GEMM), and *in vivo* (table 3). While *Broxmeyer et al* did not teach the effect of administering ferritin-H in a sickle cell disease patient, it is apparently not desirable to further suppress erythroid progenitor cells when a sickle cell anemia patient already suffers from severe anemia.

Therefore, in view of the state of the art, the limited guidance, the lack of predictability of the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation as it is now claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 22 is newly rejected under 35 U.S.C. 102(b) as being anticipated by *Broxmeyer et al* (PNAS 1991;88:770-4).

Broxmeyer et al teach a pharmaceutical composition comprising a recombinant human heavy-chain ferritin (column 2, page 770), and administering such *in vitro* and *in vivo* to bone marrow cells (page 771) or mice (page 773). Accordingly, *Broxmeyer et al* anticipate instant claims.

Claims 1, 19, 22, 27 are newly rejected under 35 U.S.C. 102(b) as being anticipated by *Adams et al* (New Eng J Med 1998;39:5-11), and as evidenced by *Files et al* (J Pediatric Hematol Oncol 2002;24:284-90) and *Sowemimo-Coker* (Transfus Med Rev 2002 Jan;16:46-60).

The claims are drawn to a method for treating sickle cell disease in humans, comprising exposing a globin-producing cell to a ferritin-H such that the globin-producing cell absorbs the ferritin-H.

Adams et al teach preventing a first stroke of sickle cell anemia in children by red blood transfusion (See particularly abstract and § Methods), wherein the red blood cells comprises ferritin-H. Although not relied upon, *Files et al* teach that for years red blood transfusion has been used to correct anemia in sickle cell patients, and serum ferritin levels increased lineally with cumulative transfusion volume in humans (e.g. abstract, § Result), indicating transfusion of red blood cell indeed supplement FtH. *Sowemimo-Coker* teaches that the lysis of RBC (hemolysis) does occur during processing, storage and transport (abstract), and thus, the nuclear ferritin-H is present in RBC transfusion unit, and RBC transfusion supplies FtH via more than one means. Instant claims are broadly drawn to any means of exposing exogenous ferritin-H to globin-producing cells,

Art Unit: 1633

which encompasses the red blood transfusion. Accordingly, *Adams et al* anticipate instant claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **William Phillips**, whose telephone number is (571) 272-0548.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

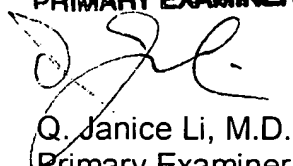
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Art Unit: 1633

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For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

**Q. JANICE LI, M.D.
PRIMARY EXAMINER**



Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL

July 10, 2006